4.0 510(K) SUMMARY

510(k) Notification K K140185

GENERAL INFORMATION

Applicant:

Avinger, Inc.
400 Chesapeake Drive
Redwood City, CA 94063
U.S.A.
Phone: 650-241-7900
Fax: 650-241-7901

Contact Person:

Sherry Kim
Sr. Regulatory Affairs Specialist
Avinger, Inc.
Phone: 650-241-7004
Fax: 650-241-7901

Date Prepared:

January 23, 2014

DEVICE INFORMATION

Trade Name:

Ocelot System, Ocelot PIXL Catheter

Generic/Common Name:

Percutaneous Catheter

Classification:

21 CFR§870.1250, Percutaneous Catheter, Class II
21 CFR§892.1560, Ultrasonic Pulsed Echo Imaging System, Class II

Product Codes:

PDU, NQQ

PREDICATE DEVICES

- Avinger Ocelot System (K122380) / Ocelot PIXL Catheter (K123532)
- C7 XR Imaging System™ with the C7 Dragonfly™ Imaging Catheter (K093857)

DEVICE DESCRIPTION

The Ocelot System consists of the Ocelot Catheter, the Lightbox Imaging Console, and the Umbilical. Unless otherwise specified, the terms "Ocelot System" and "Ocelot Catheter" are inclusive of all Ocelot Catheters in the Ocelot Catheter family. The Ocelot Catheter is an over-the-wire, sterile, single-use device that is compatible with a 0.014" guidewire. The Ocelot Catheter incorporates an optical fiber used to facilitate Optical Coherence Tomography (OCT)-assisted orientation and imaging as an adjunct to fluoroscopy. The Lightbox Imaging Console is an optical transceiver, transmitting light to the intraluminal environment through the optical fiber on the Ocelot Catheter and receiving and interpreting the signal from the tissue using a PC-based processing system. The Lightbox Imaging Console consists of a cart with two monitors, a PC, an isolation transformer, and the OCT system. The Umbilical is a 3-meter long optical and electrical extension cable that connects the Ocelot Catheter and the Lightbox Imaging Console. The Umbilical is reusable, non-sterile, and is intended for use outside of the sterile field.

PROPOSED INDICATIONS FOR USE

The Ocelot System is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including sub and chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention using OCT-assisted orientation and imaging. The system is an adjunct to fluoroscopy by providing images of vessel lumen and wall structures. The Ocelot System is contraindicated for use in the iliac, coronary, cerebral, renal or carotid vasculature.

SUBSTANTIAL EQUIVALENCE

Predicate device: Ocelot System (K122380) / Ocelot PIXL Catheter (K123532)
There are no differences in the device design and technological characteristics between the Ocelot System presented in this submission and the predicate Ocelot System and Ocelot PIXL Catheter cleared under K122380 and K123532, respectively. The Ocelot System's Indications For Use cleared under K122380 and K123532 are being revised to include imaging of vessel lumen and wall structures.

Predicate device: C7 XR Imaging System™ with the C7 Dragonfly™ Imaging Catheter (K093857)

Verification and validation testing has been completed for the Ocelot System. Validation testing included the use of the predicate device, the C7 XR Imaging System™ with the C7 Dragonfly™ Imaging Catheter (K093857). The completed testing results demonstrate that the Ocelot System is substantially equivalent to the predicate device, C7 XR Imaging System™ with the C7 Dragonfly™ Imaging Catheter (K093857) with respect to imaging of vessel lumen and wall structures. The system specifications and technological characteristics for the subject device and predicate device also demonstrate substantial equivalence with respect to OCT imaging system technology and imaging specifications.

NONCLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary performance testing was conducted on the Ocelot System to support a determination of substantial equivalence to the predicate devices. The non-clinical, bench testing provided in this submission includes:

- Design verification and bench validation studies
- Packaging and shelf-life
- Software verification and validation
- Electrical safety, electromagnetic compatibility, and laser safety testing

The non-clinical, bench testing conducted on the Ocelot System provided in the prior K122380 and K123532 submissions and still applicable to the current Ocelot System included:

- Biocompatibility
- In-vivo animal validation study
- Sterilization

The collective results of the non-clinical testing demonstrate that the Ocelot System meets the established specifications necessary for consistent performance for its intended use.

CLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

Clinical testing results to demonstrate safety and effectiveness of the Ocelot System were included in the prior K122380 submission. No new clinical testing is included in this 510(k) submission.

CONCLUSION

As demonstrated in the testing summaries, no new issues of safety or effectiveness are raised in this submission and the Ocelot System is substantially equivalent to the predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 1, 2014

Avinger Inc
Sherry Kim
Sr. Regulatory Affairs Specialist
400 Chesapeake Drive
Redwood City, CA 94063

Re: K140185
Trade/Device Name: Ocelot System: Ocelot Catheter, Ocelot PIXL Catheter, & Light Box Console
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU/NQQ
Dated: March 27, 2014
Received: March 28, 2014

Dear Ms. Sherry Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

forBram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

3.0 INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K140185

Device Name: Ocelot System

Indications For Use:

The Ocelot System is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including sub and chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention using OCT-assisted orientation and imaging. The system is an adjunct to fluoroscopy by providing images of vessel lumen and wall structures. The Ocelot System is contraindicated for use in the iliac, coronary, cerebral, renal or carotid vasculature.

Prescription Use _X_ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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